RQMP Global Feedback

Introduction

The following ideas are adapted from a sampling of first-year operational plans across organizational units. Please read and consider if, and how, these ideas could improve overall research quality management in your unit if applicable. The examples are organized by section in the RAOST REDCap database. Note that some of the sections from the database have been combined due to similarity.

L (Section 1) and M

The Lead Research Administrator must be a Subject Matter Expert in Research Administration.

Also consider the advantages of making the Lead Research Administrator (LRA) the same person as the Research Administrative Leader (RAL) who is designated by the Duke Office of Research Administration. If that is not the best strategy for your unit, please plan communication strategies for how information that is shared during the RAL meet-ups, and other correspondences, will be shared with the LRA to ensure the RQT is fully abreast of all research administrative information that impacts research quality.

J.1.: Describe how [RQO name] will serve as the Research Quality Officer.

- Ensure scientific oversight of all research activities, including organizational understanding and ongoing implementation of appropriate policies and procedures necessary to maintain scientific integrity.
- Convene an RQT meeting monthly (LRA as well as delegates) to discuss ongoing research quality issues, review activity on each members' responsibilities; ensure progress of plan development, training and required institutional compliance.
- Meet with ORA and RASR (if applicable) at least every 6 months to review activities, provide organizational unit updates, and discuss implementation of requested actions. In addition, attend any requested meetings or events hosted by DOSI or ORA in regards to the RQMP.
- Ensure organizational unit faculty and staff awareness of the RQMP program, and the roles and identities of the RQT. Maintain an open-door policy and encourage people to come see me if they have concerns about research integrity.
- Leverage existing opportunities to address emergent issues as they arise pertaining to research integrity and quality such as during organizational unit meetings and meetings of the organizational unit leadership.
- Request input from key opinion leaders of both the faculty and administrative sides within the organizational unit to better understand relevant issues and champion resolution.
- Create opportunities to promote highest ethical and research quality standards within the unit, (e.g., curate "Research Principles" on the organizational intranet, provide on-going workshops to instruct scientists on best practices, provide an annual lecture on research ethics).

L.1.: Describe how [LRA name] will serve as the Lead Research Administrator.

- Serve as the primary research administration liaison between the organizational unit and the SOM (DOSI, ORA, etc.). Disseminate information provided by these offices to the broader community and ensure the organizational unit meets all institutional and organizational unit quality management deadlines and goals.
Serve in an authorized capacity with the SOM, ensuring efficient, effective and compliant work procedures. Work operationally and strategically to identify systemic issues that can be brought forward to school leadership and be an accountable partner with the SOM research administrative leadership.

Attend institutional Research Administrators Meet-up and participate in working groups.

Develop and oversee organizational unit research metrics to track quarterly/monthly performance and develop communication plans regarding new metrics. Oversee and provide overviews to RQO, and other appropriate persons, of all performance plans associated with metric outcomes.

Attend regular meetings with the RQO and other members of the RQT.

J.2 and L.2 combined: Ensure that research faculty and supporting scientific staff are aware of institutional policies and procedures.

- Disseminate information about institutional policies and procedures at regularly scheduled meetings, (e.g., monthly faculty and staff meetings, weekly lab meetings, Faculty Advisory Board (FAB) meetings, bimonthly organizational clinical research staff symposiums, etc.) and disseminate meeting minutes to reiterate information shared and ensure those not in attendance are informed.
- Disseminate information about institutional policies and procedures via: sending emails and newsletters using various listservs, posting information on organizational unit intranets sites, Internal Wikis, SharePoint sites, physical display monitors (if applicable), etc.
- Meet individually with new faculty and staff to review all applicable requirements and training in order for them to perform their role successfully.
- Ensure training coordinators are closely monitoring completion of compliance training and providing reports to the RQT quarterly (or more frequently for time sensitive training).
- Utilize the research administration team to facilitate understanding as they interact with their faculty on a periodic basis. Implement a program where each PI meets periodically with the administrative team, both to review expenditures and projections and to discuss knowledge of and compliance with institutional policies and procedures.
- Work with the Pre and Post award units to verify faculty and research staff compliance in submission of grants and other supporting research-related changes in institutional policies and procedures.
- Provide opportunities for training on changes to SOPs combined with dissemination of process maps/documentation explaining new procedures.

J.3 and L.8 combined: [RQO] Serve as primary liaison with conflicted faculty within unit and DOSI-COI/OA; [LRA] Oversee DOSI-issued COI/Outside Activities (OA) management plans within the unit.

- Assess existing processes and develop a plan for the intake, central review, documentation, and filing of faculty and staff COI management plans. As part of this plan, outline the internal dissemination and process for: 1) tracking internal communication with faculty and staff (research and administrative) who need to be made aware of existing plans and 2) where plans will be centrally filed (e.g., maintained and indexed on a server in a shared directory).
- Meet regularly with conflicted faculty to ensure the development and implementation of management strategies.
• Identify faculty and staff who are non-compliant with COI processes (including for submission of the annual COI form), work with them to find a path to compliance, and participate as necessary in meetings between them and DOSI-COI/Outside Activities to find management strategies.
• Educate faculty and staff on COI topics in periodic organizational meetings, (e.g., addressing COI in faculty meetings to increase awareness). Agenda items could include updates on regulations about outside activity reporting as well as foreign travel. Incorporate organizational unit specific policies and expectations to all faculty in the research faculty onboarding process.

J.4: Ensure faculty and scientific staff engaged in research are in compliance with RCR training.
• Require completion of RCR training of all new faculty and staff within 90 days of hire. Include RCR training completion on employee onboarding checklists.
• Monitor RCR training compliance by reviewing the RCR tracker monthly. At the time of the review, manually add additional faculty and staff that were not identified through current automatic presets as being engaged in research or were incorrectly identified as "exempt" to the required RCR training lists. Exempt personnel from the RCR training list who are incorrectly identified as engaged in research.
• Circulate announcements by email for RCR Town Halls and Workshops or those that seem of particular value to faculty and staff within the organizational unit.
• Email staff who are out of compliance and give a deadline to complete (e.g., within the next 5 business days for the on-line training and 20 business days for the face-to-face training; or receive adequate reason for why training cannot be completed in this timeframe). Failure to reply to the first email results in 2nd email that includes their supervisor. Escalate noncompliance to deadlines to the organizational unit leadership by expiration date. If appropriate, faculty research activities may be put on hold until compliance requirements are met.
• Coordinate unit-led RCR-200 trainings. The RQT will implement by coordinating a RCR discussion within the research unit using the materials provided by DOSI-ASIST in the RCR Toolbox to present needed information to faculty and staff.

J.5: Ensure that faculty and staff engaged in research attest to Scientific Culture & Accountability Plan (SCAP).
• Work in coordination with DOSI to ensure all individuals identified as needing to attest to the organizational unit SCAP meet the institutional deadline for attestation.
• Require faculty and staff to sign the SCAP attestation during their first week of hire (or transfer if internal) in the organizational unit.
• Assume the responsibility for review and updating of the document on at least an annual basis. The SCAP will be discussed and open to continuous modification/improvement, based on discussions in the periodic Research Quality Team meetings. Use relevant research integrity/quality scholarly publications, known areas for improvement and known best practices, to guide modifications of the SCAP.
• Keep the most up to date version of the SCAP on the institutional website for easy access for not only faculty and staff, but external persons who may be interested in the scientific culture of the organizational unit.
• Require creation and attestation of lab-based SCAPs and best practices to confirm that labs are actually living and promulgating a culture of scientific accountability within and among their respective research teams.

J.6: Facilitate Clinical Quality Management Planning. [Only applicable to organizational units with CRUs]

• Review findings to determine if there is an emerging trend or systemic issue that requires further escalation. Note: Within organizational units, CQMP is managed by an assigned Clinical Research Coordinator and the Research Practice Manager with oversight from the Research Quality Team and CRU Director. Findings that are identified will be escalated to the organizational unit leadership and administration to address with faculty and staff.
• Communicate regularly with the CRU Director and Research Practice Manager (RPM) to discuss CQMP-related activities. Confirm that experienced and well-qualified reviewers are being designated in the organizational unit, and that QM reviews being conducted well and on-time, etc.
• Discuss CQMP with faculty and staff at forums like organizational unit meetings to better understand significant and reoccurring issues across studies and evaluate the need for future CAPAs. Champion organizational unit-wide and SOM-wide CAPAs when indicated.

J.7: Ensure best practices related to Data Management.

• Ensure that Service Centers (aka Shared Resources or Cores) abide by their Data Management Plans (DMPs) and that all faculty and staff in those Service Centers are trained in and familiar with the content of their DMPs through the use of either training logs or DMP attestation with the Service Center.
• Encourage each research area within organizational unit to have a DMP that all faculty and staff are aware of and using.
• Create general data management principles applicable to the organizational unit overall.
• Provide faculty with resources to find guidance on management, provenance, security and storage of data.
• Recommend that all laboratories use an electronic research notebook and that data are stored digitally and properly backed up.
• Outline expectations regarding data storage and management in the SCAP.

J.8: Ensure faculty and staff successfully complete required corrective actions

• Host an all hands staff meeting at the beginning of each fiscal year, in which the RQT discusses the importance of the responsible conduct of research and associated issues.
• Create and maintain a folder housing all corrective action plans with a spreadsheet detailing a summary of PI, plan date, and a description of the nature of the plan.
• Work with organizational unit leadership to ensure that corrective action plans are carried out in accordance with the appropriate regulatory body. Document via the appropriate resource (e.g., IRIS for IRB-related matters) or via written or electronic communication in addition to face-to-face meetings.
• Act as the primary advisor to all research staff for action plans and follow up from central research regulatory and administrative offices (IRB, IACUC, OARC, Senior Response
Committee/Incident Response and Issue Resolution Committee). Enforce appropriate actions in the event of improper conduct and work with faculty to find an acceptable management plan. If necessary, support or advise against suspending activities that are chronically out of compliance regarding the offending faculty.

- Present repeated instances of failure to abide by regulations and policies to the Duke Office of Scientific Integrity (DOSI), or other appropriate entities at Duke for guidance on appropriate corrective actions.

L.3. Ensure administrative staff compliance with RCR-A training [RCR-A training not yet available]

- Work with ASIST team to ensure all new and/or transitioning research administration staff have signed up and complete RCR-A training within the required due date.
- Contact those not in compliance to reach a goal of 100% of administrators being trained.

L.4. Promote use of the Intent to Submit tool and attendance at proposal / award kick-off meetings.

Intent to Submit (ITS) Tool:

- Incorporate the ITS tool into the existing pre-award training for new hires.
- Provide detailed communication to faculty and staff regarding the ITS tool using email listserv, intranet postings, organizational unit-wide meetings, etc.
- Provide information about the ITS tool in regular faculty meetings.
- Make the ITS tool available via the intranet and demonstrate how to link it on myRESEARCHhome portal.
- Oversee the training needs for faculty and staff regarding the tool.

Award Kick-Off Meetings:

- Provide training sessions and guidelines to new research administrators about how to conduct the post-award portion of the kick-off meetings.
- Develop an SOP that clearly defines responsibilities for research administrators and PIs. Incorporate tools (such as checklists and example documents) and review the usage of the tools across the volume of kick-off meetings for the organizational unit.
- Require all first-time applicants and complex projects to have an initial meeting to ensure proper project management and adherence to timelines.


Request for Rush Service:

- Review requests for rush service and advise appropriate decision-makers whether to grant the request depending on the circumstance. Note: Once the internal approval is obtained, the grants manager works directly with the assigned ORA representative to address the rush request.
- Communicate with faculty about Request of Rush Service and associated time frame for ORA review in an effort to avoid the need for Rush Service in the future.
- Regularly review Rush Service requests to identify causes and trends. Update processes as causes are identified.
Return for Changes (RFC)

- Track and use RFC data to facilitate communications.
- Meet with the assigned team within ORA to understand RFC reasons and request checklist tools they used to review the proposal.
- Update the SOP concerning RFC use within the organizational unit based on updated policies and input from ORA.

L.6. Facilitate implementation of the 5-day internal deadline for proposals, including waiver requests.

- Work directly with grant administrators and managers to ensure their understanding of the new rules for proposals like the 5-day internal deadline and waiver requests. Guide research administrative staff regarding this policy through joint meetings with faculty to help enforce the timeline and answer any faculty questions related to this rule. Employ the use of checklists and defined timelines during joint meetings.
- Review feedback from research administrators regarding proposal timelines and provide support and immediate response to any issues that require escalation to organizational leadership.
- Solicit feedback from faculty and their teams regarding proposal timelines and relay resources or barriers that they need assistance with to allow for success.
- Proactively review and track the waiver request data provided by the SOM and identify areas for improvement.
- Ensure organizational policies and SOPs are updated and shared with faculty and staff.
- Keep organizational leadership informed of the progress the organizational unit is making with the new rules and alert them to issues that will rise to their level for correction.

L.7. Promote the use of myRESEARCHhome with faculty, research staff and grant administrators.

- Invite My Research Navigators to present a demonstration to current faculty and staff and request smaller group training opportunities when needed.
- Add MRH information to the orientation/onboarding materials for new faculty and staff.
- Require all faculty and research administrators in the organizational unit to use MRH as their homepage for at least 90 days.
- Review the data provided by the SOM to evaluate the organizational unit’s level of usage.
- Keep faculty and staff aware of new MRH features using various communication methods such as email listserv, intranet postings, organizational unit-wide meetings, etc.

L.9.: Ensure all staff performing research administration duties have a reporting relationship to an administrator.

- Maintain the proper reporting lines and training requirements for staff performing research administration duties.
- Ensure that the Reporting Relationship Assignment letters are up-to-date and documented through tools like org charts.
- Do annual reviews to ensure administrative staff’s reporting relationship to another administrator.